caBIG Data Sharing and Intellectual Capital Working Group (DSIC WG)

Survey on Data Sharing Restrictions

Respondent's Contact Information

Name:
E-Mail:
Title:
Degree(s):
Cancer Center:
Division (e.g., tech transfer, industrial relations, etc.):
Cancer Center Role in caBIG (workspace / working group; developer, adopter):

Survey Purpose

The National Cancer Institute (NCI)-designated Cancer Centers have agreed to partner with the NCI in the development of the Cancer Biomedical Informatics Grid (caBIG) (<http://cabig.nci.nih.gov/>). The caBIG pilot initiative seeks to integrate data from more than 50 cancer centers in ways that make it useful for clinical and basic researchers to consume of the vast array of genetic and clinical information. As a result, caBIG will offer Cancer Centers a library of tools and resources, from clinical trial management systems to tissue bank and pathology tools, all of which are built on common standards and are interoperable. Participation in caBIG is voluntary, and the data sets submitted and supported by caBIG will be openly accessible to the caBIG community. It is recognized that not all data can be shared because of agreements with industry partners; however, caBIG participants are encouraged to share as much data as possible.

Data Sharing in caBIG Activities

The following provide a number of data sharing scenarios that are likely within caBIG. It is hoped that a brief review of the possible uses of shared data by the caBIG community will be helpful as you complete the survey provided. The survey will give us a sense of each center's freedom to share data, and aid us in developing recommendations for best practices for data sharing within the caBIG community.

Data used in caBIG activities will likely be shared in one of the following scenarios (or some combination thereof):

(1) Sharing of Pilot Data for Testing Purposes: As caBIG software applications are developed and ready for initial testing by the designated Adopter sites, followed by more global piloting at all interested sites, sets of test data will be submitted from the pilot centers, consisting of actual anonymized (per HIPAA requirements) data with the content specific to the application being tested.

Examples:

- Sample file of protocol data with administrative and scientific characteristics

- File of patients accrued to clinical trials over the past year, with disease, treatment, & outcomes data
- File of biomarkers for patients with a particular disease

(2) Sharing of Study Data for Multi-Centered Consortia of Cancer Centers: Several cancer centers who have agreed to collaborate on a specific multi-centered protocol agree to share their required data for transmission to a pooled central repository located at the Data Coordinating Center, using caBIG compatible tools, with links to the IDs retained at the local site, and the pooled data sent as de-identified records per HIPAA requirements.

Examples:
- Data from a multi-centered Phase II clinical trial data with laboratory correlates
- Shared data on patterns of care and outcomes for a multi-centered outcomes research study
- Pooling of genomic data across several centers following the same protocol for testing

(3) Web-services Based Data Sharing: Utilization of web-based services to facilitate near real-time automated discovery of data residing at local cancer centers, without actually transmitting data to a physical central storage location.

Examples:
- Centers expose data on their active clinical trials to a web-services based search engine to allow patients to search for studies for a particular disease nationwide
- Data on genomic variants studied at a particular center are exposed to a web-services engine to facilitate potential nationwide collaborations

(4) caBIG Data Warehousing: Data that transitions rapidly or needs to be centrally pooled for extensive data mining and discovery are transmitted to a central caBIG data warehouse, with detailed access policies defined to determine who may mine the data and for what purposes.

Examples:
- A central data warehouse of Serious Adverse Events (SAE) is created across all centers, with data on the nature, severity, and attribution of the SAE along with information on insitution, protocol ID, agent(s) received, patient diagnosis and stage, and timing of the event, for pattern recognition of undetected clusters or spikes of SAEs
- Central warehouse of genomic data by disease type, with patient information and links back to the actual samples retained at the Cancer Center for genotype-phenotype correlative analyses

The NCI structured the caBIG initiative to include the Data Sharing and Intellectual Capital (DSIC) Working Group of caBIG, which has among its chartered responsibilities the exploration of issues concerning data sharing and intellectual capital in the caBIG initiative. To the extent that an individual Cancer Center has entered, or will enter, into agreements with industry partners granting rights in genetic and clinical data, the Center may not be able to make such data available for the caBIG network. Therefore, the following survey is designed to develop a sense of each of the participating caBIG institutions' freedom to share its data. Specifically it is designed to answer the question of what restrictions may be placed on each institution's data as a result of collaborations with industry and other academic institutions. For the sake of simplicity, this survey assumes that all privacy, confidentiality, HIPAA and/or

IRB requirements have been met. Please answer to the best of your ability and add comments as appropriate. In developing your responses, please consult your Center's caBIG participants to discuss any questions you may have about the survey. **All information obtained from this survey will be kept confidential and will only be distributed in de-identified, or aggregate, form.** Please submit your responses **thirty (30) days** following receipt of the survey. caBIG's DSIC Working Group will consider the results of this survey in the course of developing recommendations for best practices for data sharing in connection with caBIG activities. We recognize that responding to the survey will require time on your part to search databases and prepare responses. Therefore, please know that your efforts are very important and will be greatly appreciated.

Questions

For each situation described below, please indicate the approximate number of formal agreements on file in your office. For the purposes of these questions, "your institution" refers to an investigator or group of investigators representing your Cancer Center. "Ownership" refers to any legal or intellectual property rights associated with the material in question.

1. Your institution provides biospecimens to another academic (not-for-profit) institutions in exchange for experimental data about those specimens and –

____Total number of agreements
____Specimens are provided, but no data is exchanged
____Data can be shared only with one specific investigator at your institution
____Data can be shared only with investigators at your institution
____Data can be shared with other institutions and third parties
____Your institution is considered the "owner" of specimens and data
____Your institution is considered the "owner" of the specimens, but not the data
____Your institution places specific restrictions on how the biospecimens can be used
____There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

2. Your institution provides biospecimens to industry (for-profit) in exchange for experimental data about those specimens and –

____Total number of agreements
____Specimens are provided, but no data is exchanged
____Data can be shared only with one specific investigator at your institution
____Data can be shared only with investigators at your institution
____Data can be shared with other institutions and third parties
____Your institution is considered the "owner" of specimens and data
____Your institution is considered the "owener" of the specimens, but not the data

___Your institution places specific restrictions on how the biospecimens can be used
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

3. Your institution receives biospecimens from another academic (not-for-profit) institutions in exchange for experimental data about those specimens and –

___Total number of agreements
___Data can be shared only with one specific investigator at the other institution
___Data can be shared with other investigators at your institution as well
___Data can be shared with other institutions and third parties
___Your institution is considered the "owner" of the data
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

4. Your institution receives biospecimens from industry (for-profit) in exchange for experimental data about those specimens and –

___Total number of agreements
___Data can be shared only with the commercial entity
___Data can be shared with other investigators at your institution as well
___Data can be shared with other institutions and third parties
___Your institution is considered the "owner" of the data
___Industry is considered "owner" of the data
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

5. Your institution receives biospecimen associated data from another academic (not-for-profit) institution for the purposes of analysis and -

___Total number of agreements
___Data can be shared only with one specific investigator at your institution
___Data can be shared only with investigators at your institution
___Data can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of analysis
___The institution providing data is considered the "owner" of any findings as a result of analysis

___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

6. Your institution receives biospecimen associated data from industry (for-profit) for the purposes of analysis and -

___Total number of agreements
___Data can be shared only with one specific investigator at your institution
___Data can be shared only with investigators at your institution
___Data can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of analysis
___Industry is considered the "owner" of any findings as a result of analysis
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

7. Your institution receives reagents or compounds from another academic (not-for-profit) institution for experimentation purposes and –

___Total number of agreements
___Results can be shared only with one specific investigator at your institution
___Results can be shared only with investigators at your institution
___Results can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of analysis
___The institution providing the reagent is considered the "owner" of any findings as a result of analysis
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

8. Your institution receives reagents or compounds from industry (for-profit) for experimentation purposes and –

___Total number of agreements
___Results can be shared only with one specific investigator at your institution
___Results can be shared only with investigators at your institution
___Results can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of analysis

___The company providing the reagent is considered the "owner" of any findings as a result of analysis
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

9. Your institution is conducting a clinical trial sponsored by another academic (not-for-profit) institution and –

___Total number of agreements
___Clinical trial data can be shared only with one specific investigator at your institution
___Clinical trial data can be shared only with investigators at your institution
___Clinical trial data can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of the clinical trial
___The institution sponsoring the clinical trial is considered the "owner" of any findings as a result of the study
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

10. Your institution is conducting a clinical trial sponsored by industry (for-profit) and –

___Total number of agreements
___Clinical trial data can be shared only with one specific investigator at your institution
___Clinical trial data can be shared only with investigators at your institution
___Clinical trial data can be shared with other institutions and third parties
___Your institution is considered the "owner" of any findings as a result of the clinical trial
___The company sponsoring the clinical trial is considered the "owner" of any findings as a result of the study
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements:

11. Your institution develops and provides an analytical tool (e.g. software or algorithm) to industry (for-profit) in exchange for financial support and –

___Total number of agreements
___Tool can be used only by one specific investigator at your institution
___Tool can be used only by investigators at your institution
___Tool can be shared with other institutions and third parties

___Your institution is considered the "owner" of the tool
___The company is considered the "owner" of the tool
___There is no official "ownership" policy stated

Please list other special arrangements made for such agreements: